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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,716	08/07/2001	Joachim Kramer	AP33451(070180.0144)	1120

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BAKER & BOTTS
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NEW YORK, NY 10112

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,716

Applicant(s)

KRAMER ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,30 and 36-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,30 and 36-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of the claims

The amendment filed April 19, 2004 is acknowledged and has been entered.

Specification

1. The disclosure is objected to because of the following informalities: The specification fails to provide sequence identifiers, which correlate, to the Seq. ID. No.'s provided in the sequence listing. (See for example listing on page 7, paragraph 0018 of the specification, in which a list of amino acid sequences is disclosed, however, no sequence identifiers are provided).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 7, paragraph 0017 in the specification. The applicant discloses the subject of the present invention might also be useful for the study of the functionality of an enzyme. For instance, one could check whether an unknown protein belongs to the group of serine/threonine kinases or whether a specific

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serine/threonine kinase is biologically active. The applicant does not disclose the test compound with the threonine or serine kinase activity in the presence of a known modulator, wherein threonine or serine kinase activity in the presence of the test compound that is substantially the same as the threonine or serine kinase activity in the presence of the known modulator indicates a modulator of threonine or serine kinase activity. There is no description in the specification or the originally filed claims disclosing the test compound with the threonine or serine kinase activity in the presence of a known modulator, wherein threonine or serine kinase activity in the presence of the test compound that is substantially the same as the threonine or serine kinase activity in the presence of the known modulator indicates a modulator of threonine or serine kinase activity.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 29-30 and 36-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29, part (c) the recitation "under conditions" is vague and indefinite. It is unclear what conditions applicant is referring to. See also deficiencies found in claim 48.

Claim 29, part (c) the recitation "sufficient time" is vague and indefinite. It is unclear what is considered to be a sufficient time. There is no guidance or definition provided for the term in the specification. See also deficiencies found in claim 48.

Claim 29, part (d) is vague and indefinite because it is unclear where the antibody binds? Does it bind to the Y and Z position of the peptide or protein? Does it bind to only the Z position? Or does it bind to the amino acid? Further, if it binds to the amino acid it is unclear if one could determine threonine or serine kinase activity. (For example, the specification on page 10, paragraph 0024 discloses that the antibody specifically recognizes a phosphorylated threonine or serine residue at the Z position and it appears to the Examiner that if the antibody is specific to any position other than the Z position, the method as recited would not work because one of ordinary skill would not be able to determine if the kinase caused phosphorylation at the Z position or not). See also deficiencies found in claim 48.

6. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step of providing a labeled antibody or labeling the peptide or protein. It is unclear how the detection can be achieved without the use of a label. On page 10 of the specification in paragraphs 0027 and 0029, the Applicant discloses the use of a label, however there is no recitation of a label in the method of claim 29. See also deficiencies found in claim 48.

Claim 40 the recitation "affinity ligand" is vague and indefinite. There is no definition or guidance provided for the term in the specification. The applicant discloses on page 11, line 2 "an affinity ligand", however Applicant does not disclose what an affinity ligand is or provide examples of an affinity ligand. See also deficiency found in claim 43.

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Claim 44 the recitation "Tyr⁵" is vague and indefinite. It is unclear what applicant intends. Does applicant mean that Tyr is to the 5th power or does applicant intend something else? Please clarify. See also deficiency found in claim 47.

Claim 44 the recitation "Pro⁶" is vague and indefinite. It is unclear what applicant intends. Does applicant mean that Pro is to the 6th power or does applicant intend something else? Please clarify. See also deficiency found in claim 47.

Claim 44 the recitation "Thr⁷" is vague and indefinite. Does applicant mean that Thr is to the 7th power or does applicant intend something else? Please clarify. See also deficiency found in claim 47.

Claim 48, part (f) the recitation "substantially" is vague and indefinite. It is unclear what is considered to be substantially the same. For example, is 51 percent considered substantial or is 75 percent considered substantial or is 95 percent considered substantial?

Allowable Subject Matter

7. Claim 29 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

8. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record neither teaches nor suggests an immunoassay method for screening modulators or threonine or serine kinase activity wherein providing a threonine or serine kinase substrate wherein the Y position is phosphorylated prior to incubating with a phosphate donor and a threonine or serine kinase which causes phosphorylation of the z position as recited in the instant claims.

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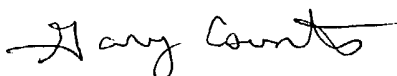
9. The closes prior art is attributed to Davis (US 2003/0023990) (see previous office action). Davis fails to teach or suggest suggests providing a threonine or serine kinase substrate wherein the Y position is phosphorylated prior to incubating with a phosphate donor and a threonine or serine kinase which causes phosphorylation of the z position as recited in the instant claims.

Conclusion

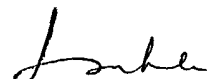
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary W. Counts
Examiner
Art Unit 1641
June 21, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/22/04